> preventing the recurrence of colon polyps. This study also collected data on the long-term cardiovascular safety of Vioxx. Importantly, in the first 18 months of the study, there was no difference in the risk for heart attack or stroke in patients taking either Vioxx or placebo. Beginning after 18 months, however, the risk of a cardiovascular event did increase among those on Vioxx.
>
> Accordingly, we are voluntarily withdrawing Vioxx effective today. We are taking this action because we believe it best serves the interest of patients. We believe it would have been possible to continue to market Vioxx with labeling that would incorporate these new data. However, given the availability of alternative therapies, and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take.

Defendant's CEO's statements were wholly false and misleading and were designed to conceal Merck's pre-1999 knowledge of Merck's cardiovascular risks.

79. On November 1, 2004, the *Wall Street Journal* published the above-described article entitled "Warning Signs: Emails Suggest Merck Knew Vioxx's Dangers at Early Stage; As Heart-Risk Evidence Rose, Officials Played Hardball; Internal Message: 'Dodge!'; Company says 'Out of Context.'" As described more fully above, the November 1, 2004 Wall Street Journal article detailed, among other things, how even though Defendant's CEO expressed that the APPROVe study findings tying VIOXX® to heart attacks and strokes were unexpected, internal Merck e-mails, marketing materials and interviews with outside scientists indicated that Merck "fought forcefully for years to keep safety concerns from destroying the drug's commercial prospects." The article made, among others, the following critical points:

> • E-mails by and between Company executives in the mid to late 1990s showed that Merck knew that Vioxx increased the risk of cardiac events, and sought to conceal such financially damaging information;
>
> • The VIGOR results, released in March 2000, showed that Vioxx patients, as compared with those taking Naproxen, suffered five times as many heart attacks. In March 2000, defendant Scolnick e-mailed colleagues that the risk of cardiovascular events associated with Vioxx

were "clearly there," and was a "mechanism-based problem," but in a news release Merck offered no hint that anyone at the Company knew that Vioxx itself increased the risk of cardiovascular events. When it published the VIGOR results, Merck stated that the study's findings were consistent with the cardioprotective qualities of Naproxen--rather than the increased cardiovascular risks associated with Vioxx;

• When the VIGOR study results were published in the New England Journal of Medicine, it stated that among patients studied who were not already at high risk for heart attacks, Vioxx did not show a significant rise in heart attacks;

• A Merck training document entitled "Dodge Ball Vioxx" instructed sales representatives to dodge questions or concerns about the cardiovascular effects associated with Vioxx; and

• Merck attempted to suppress discussion about the VIGOR study results by, among other things, telephoning academics to complain about lectures the Company deemed to be "irresponsibly anti-Merck and specifically anti-Vioxx;" withdrawing financing from seminars at which doctors and academics who were critical of Merck's handling of Vioxx were scheduled to speak, and even filing suit to "correct" publications raising concerns about Vioxx's cardiovascular risks and criticizing Merck's handling of those concerns.

80. Each of the Defendant's statements made in 2004 concerning VIOXX® was materially false and misleading when made, because each statement failed to disclose the extent of the Company's knowledge that VIOXX® was in fact associated with a significant risk of cardiac events. The true but concealed and/or misrepresented facts included, but were not limited to:

• The Merck Defendants' removal of Dr. Cannuscio's name from the Harvard-Brigham Women's Study was a deliberate attempt by the Merck Defendants to conceal Vioxx's known risks;

• The Kaiser Permanente study confirmed the results of Study 090 and VIGOR, and thus demonstrated that Vioxx caused severe cardiovascular complications;

• Adequate justification for withdrawing Vioxx from the worldwide markets existed well before September 30, 2004, and the Merck

Defendants' attempts to base the withdrawal upon the putative results of the APPROVe study were knowingly false when made;

• The Company was aware that Vioxx itself created an increased risk of heart attack, and that its explanation for the VIGOR study results--that the Vioxx patients suffered greater incidences of cardiovascular events because of cardioprotective qualities of Naproxen--was inaccurate;

• The Company's statements refuting the results of the Brigham & Women's Hospital Study finding an increased risk of heart attack in patients taking Vioxx were unfounded;

• Merck's statements that the lawsuits filed against the Company with respect to Vioxx were meritless were, in fact, unfounded;

• The Company's announcements and press releases throughout 2004, stating that Merck 'stands behind the safety of Vioxx' were unfounded, because Merck knew that Vioxx, in fact, was associated with cardiovascular events and was therefore not safe;

• Merck's press releases "reconfirming the favorable cardiovascular safety profile of Vioxx" during 2004 were unfounded, because the Merck Defendants knew that Vioxx was associated with high cardiovascular risks;

• The Vioxx promotional activities that the FDA condemned in the September 17, 2001 FDA Letter stemmed from Merck Defendants' deliberate efforts to conceal Vioxx's known risks, which continued in 2004;

• Merck's unpublished Study 090 concluded that Vioxx users were 6 times more likely to have severe cardiovascular events than other users of NSAIDS;

• Internal Merck e-mails authored in 1996 and 1997 reveal that even before the FDA approved Vioxx for prescription use, Merck knew of the Vioxx-related medical risks;

• Substantial data existed in 1999 that Vioxx was associated with a higher risk of cardiovascular events than other NSAIDs;

• On December 16, 1999, Merck had received the December 16, 1999 FDA Letter admonishing defendants for misleading the public by using deceptive promotional materials that suggested Vioxx had a superior safety profile to other NSAIDS, which was not demonstrated by substantial evidence;

• Defendant knew that the negative cardiovascular events were not due to the cardioprotective properties of Naproxen, but were instead directly attributable to the cardiovascular risks that the Merck Defendants observed in Study 090; and

• Vioxx's safety profile was not "excellent" as the Defendant claimed, but was instead marked by an unacceptably high risk of negative cardiovascular events.

COUNT I
FRAUD

81. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

82. Defendant committed fraud against the State of Mississippi and all State agencies and instrumentalities that approved VIOXX® for reimbursement in reliance on the false and misleading safety and efficacy data provided, communicated and/or published by Defendant. Defendant knew that the safety and efficacy data it provided, communicated and/or published were false. Defendant provided such false data with the intent of inducing Mississippi agencies and instrumentalities to rely on the false information in determining pharmacy benefits related to VIOXX®.

83. Mississippi agencies and instrumentalities reasonably relied on such false information in approving VIOXX® for reimbursement. Defendant's fraudulent conduct is continuing, as it regularly and periodically continued to issue false data for publication concerning the safety and efficacy of VIOXX®.

84. As a result of Defendant's fraudulent conduct, the State of Mississippi, its agencies and instrumentalities, as well as the citizens of Mississippi, have been damaged by paying excessive amounts for Defendant's drug, VIOXX®, when it was no more effective than other less expensive NSAIDS, and when it exposed those who ingested the drug to substantial

adverse health effects, including the risks of heart attack and stroke. Defendant's conduct was knowing, intentional, with malice, demonstrated a complete lack of care, and was in conscious disregard for the rights of Plaintiff. Plaintiff is therefore entitled to an award of punitive damages.

COUNT II
VIOLATION OF MISSISSIPPI'S CONSUMER PROTECTION ACT

85. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

86. Defendant's representations as set forth herein, concerning the characteristics and benefits of VIOXX®, including its safety and efficacy, were false, misleading and untrue when made, and constitute a violation of Mississippi's Consumer Protection Act, § 75-24-1, *et seq.*, Miss. Code Ann.(1972)

87. Attorney General Jim Hood brings this action for a declaratory judgment that the Defendant's conduct as set forth herein, violated §75-24-1, *et seq.*, Miss. Code Ann.(1972) and seeks, pursuant to §75-24-9, an injunction to restrain the foregoing continuation of dissemination of false safety and efficacy information concerning VIOXX® to the public. Further, Plaintiff is entitled to civil penalties against Defendant, pursuant to § 75-24-19.

COUNT III
UNTRUE, DECEPTIVE, AND MISLEADING ADVERTISING
IN VIOLATION OF § 97-23-3 MISS. CODE ANN. (1972)

88. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

89. As stated herein, Defendant made false, deceptive and untrue statements and representations concerning the safety, risks, and effectiveness of VIOXX®, to the public generally, and Mississippians, specifically. These statements and representations were

published, circulated, disseminated, and placed before the public generally, and Mississippians, specifically, in print and media advertisements, in publications, and by other means. Such statements and representations were made with the intent to sell or distribute VIOXX® to Mississippians, directly or indirectly, and were made with the intent to increase the consumption of or demand for VIOXX® by Mississippians. Defendant knew when the statements and representations were made that the information concerning VIOXX® was untrue, deceptive or misleading.

90. The foregoing conduct of Defendant as alleged above constitutes unfair, deceptive and misleading advertising of VIOXX® in violation of § 97-23-3 Miss. Code Ann.(1972). As a result of Defendant's conduct, the State of Mississippi, its agencies and instrumentalities, as well as the citizens of Mississippi, have been damaged by paying excessive amounts for VIOXX®, when it was no more effective than other less expensive NSAIDS, and when it exposed those who ingested the drug to substantial adverse health effects, including the risks of heart attack and stroke.

COUNT IV
MEDICAID FRAUD

91. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

92. Defendant knowingly made, or caused to be made, false or misleading statements or representations in order to obtain payments for its pharmaceutical drug, VIOXX®, under Mississippi's Medicaid program. Such conduct constitutes Medicaid fraud in violation of § 43-13-223, *et seq.*, Miss. Code Ann.(1972).

93. As a result of the hereinabove described fraud upon the Plaintiff, Defendant is liable to Plaintiff in an amount equal to the full amount it received as a result of payments made

by Mississippi Medicaid for its drug, VIOXX®, plus an additional civil penalty equal to triple the full amount received by Defendant on account of these payments.

COUNT V
RESTITUTION/ UNJUST ENRICHMENT

94. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

95. As a result of the false and misleading statements and representations of the Defendant concerning its drug, VIOXX®, the State of Mississippi, its agencies and instrumentalities, and Mississippi citizens, paid excessive amounts in connection with purchases and/or reimbursements of purchases of Defendant's prescription drugs.

96. As a result of the excessive payments for VIOXX®, Defendant obtained increased sales and market share for its product, and, therefore, increased profits, and was unjustly enriched at the expense of the State of Mississippi, its agencies and instrumentalities and Mississippi citizens.

97. In equity and fairness, it is the Defendant, not the taxpayers of Mississippi, who should bear the costs of VIOXX®-related diseases. By avoiding its own duties to stand financially responsible for the harm done by its prescription drug, the Defendant has wrongfully forced the State of Mississippi to perform such duties and to pay the health care costs of VIOXX®-related diseases. As a result, the Defendant has been unjustly enriched to the extent that Mississippi's taxpayers have had to pay these costs.

98. By this Complaint, the Attorney General seeks damages in an amount which is sufficient to provide restitution and reimbursement to the State for the sums the State has expended as a result of the Defendant's wrongful conduct, with said amount to be determined at

trial and for damages in restitution for the sums of money to be paid by the State in the future on account of the Defendant's wrongful conduct.

COUNT VI
NEGLIGENCE

99. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

100. Defendant had a duty to exercise reasonable care in the marketing, advertising, sale and distribution of Defendant's pharmaceutical drugs, including VIOXX®.

101. Defendant breached that duty by the conduct alleged herein.

102. As a result of Defendant's breach, VIOXX® was marketed, advertised, sold, and distributed in the State of Mississippi, and the State of Mississippi, its agencies and instrumentalities and the citizens of Mississippi have been damaged by paying excessive amounts for VIOXX®, when it was no more effective than other less expensive NSAIDS, and when it exposed those who ingested the drug to substantial adverse health effects, including the risks of heart attack and stroke.

103. In addition, beneficiaries of the State's prescription drug programs sustained and/or will sustain adverse health effects as a result of the ingestion of VIOXX®, which was the intended and foreseeable use of Defendant's drug. Plaintiff was required and/or will be required in the future to provide medical assistance to these Medicaid recipients.

104. In breaching its duties to the Plaintiff, as described above, Defendant acted negligently and/or in reckless disregard for the truth, in that Defendant knew or should have known through information available exclusively to them and otherwise that VIOXX® did not have the safety and efficacy it promoted, and that if used in the manner intended by Defendant, those who ingested the drug were at an increased risk for severe adverse health effects, including

heart attacks and strokes. Defendant further knew or should have known that its aforesaid breach of duty would be substantially certain to result in the injuries complained of herein.

COUNT VII
INDEMNITY

105. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

106. As a direct and proximate result of the breaches of duty and omissions Defendants as alleged above, Plaintiff was obligated to pay, has paid, and will be required to pay millions of dollars for VIOXX®, and for the provision of necessary medical care, facilities and services for certain of those aforementioned Mississippi citizens injured by Defendant's drug, and unable to afford and otherwise obtain such necessary medical care, facilities and services.

107. Plaintiff was legally obligated to pay the aforementioned sums and did not conduct itself in any wrongful manner in being so obligated to pay and in paying the aforementioned sums. As stated hereinabove, Defendant has been unjustly enriched as a result of said payments.

108. In all fairness and justice, Defendant should indemnify Plaintiff for the provision of necessary medical care, facilities and services for those aforementioned Mississippi citizens injured by VIOXX®.

COUNT VIII
VIOLATION OF MISSISSIPPI'S PRODUCTS LIABILITY ACT

109. Defendant Merck, at all times relevant hereto, manufactured, tested, designed, marketed, promoted, distributed, sold and/or prescribed VIOXX® for use and consumption by consumers. At the time Defendant manufactured, promoted, tested, designed, packaged, promoted, marketed, distributed, sold and/or prescribed VIOXX®, in violation of Mississippi's

Product Liability Act, Miss. Code Ann. § 11-1-63, VIOXX® was designed in a defective manner and was unreasonably dangerous to plaintiffs and other users or consumers because, among other things, VIOXX® was likely to cause harm to users when consumed for its intended use and Merck failed to adequately warn of the potential side effects.

110. The VIOXX® consumed by consumers was not materially altered from the time of its manufacture and distribution up until the time of consumption.

111. VIOXX®, at the time of its manufacture, distribution, and sale and at all times material hereto, was defective and unreasonably dangerous to consumers for at least the following reasons:

a. Defendant's VIOXX® was not sold with an appropriate warning regarding the serious increased risk of injury, including, but not limited to, strokes, heart attacks, and cardiovascular disease.

b. The VIOXX® manufactured, tested, designed, marketed, promoted, distributed, sold and/or prescribed by Defendant was not safe as manufactured, designed, marketed, distributed, sold and prescribed;

c. Defendant failed to adequately test the safety of VIOXX® which would have shown that the substantial risk of serious injury and/or illness including, but not limited to, strokes, heart attacks, and cardiovascular disease;

d. Defendant knew or should have known that permanent damage, including harmful and permanent effects could result from the intended use of the drugs, but Defendant sold them anyway; and

e. Defendant knew or should have known that is was unreasonable to place VIOXX® in commerce and into the hands of consumers.

112. The VIOXX® manufactured, tested, designed, packaged, marketed, promoted, distributed, sold and/or prescribed by Defendant was never reasonably fit for the purposes for which it was sold, and the risk and dangers associated with its use outweighed the utility it provided.

113. Defendant Merck, through its sale and promotion of the drug VIOXX® to agencies and instrumentalities of the State of Mississippi, breached its warranty of fitness for the purpose of proper medicinal uses free of out-of-balance side effects, and failed to conform to its own factual representations that the use of the product was safe. These actions, related to the defective conditions, rendered the product unreasonably dangerous to the consumers of the State of Mississippi, and caused additional expense related to their use by the State.

114. As a direct and proximate result of Defendant's unlawful and illegal conduct, the State of Mississippi has been, and continues to be, damaged.

COUNT IX
INJUNCTIVE RELIEF

115. Plaintiff hereby repeats, incorporates by reference and realleges each and every allegation set forth above in this Complaint.

116. The Defendant has engaged in many years of promoting and distributing for sale the prescription drug VIOXX®, under the guise of its safety and efficacy, despite its knowledge that the drug could and did cause physical harm to persons taking the drug as prescribed. Such conduct is a violation of the laws of the State of Mississippi, and has created a health care burden for the State totaling millions of dollars.

117. It is necessary and essential to stop the Defendant from promoting the sale of VIOXX®, a remedy which can only be effectively accomplished by enjoining the Defendant

from not only promoting the sale of Vioxx, but additionally in engaging in the sale or distribution of Vioxx.

118. If such injunction enjoining the Defendants from promoting the sale of its prescription drug VIOXX® is not granted, the citizens of the State of Mississippi who thereafter ingest the drug will be irreparably harmed in that they will be substantially certain to suffer adverse health consequences.

119. It is in the public interest to enjoin the Defendant from promoting the sale of VIOXX®.

120. By this Complaint, the Attorney General seeks an injunction to be issued against the Defendant to prohibit it from promoting the sale of VIOXX®, and from engaging in the sale and distribution of said prescription drug.

PRAYER FOR RELIEF

Wherefore, Plaintiff prays for relief as follows:

(1) an Order enjoining the Defendant from promoting the sale of VIOXX®, and from engaging in the sale and distribution of VIOXX®;

(2) an Order declaring that the Defendant's conduct violated Miss. Code Ann. § 75-24-1, *et* seq, (1972) and Miss. Code Ann. § 11-1-63 and an injunction to restrain Defendant from engaging in practices in violation of Miss. Code Ann. §75-24-9 (1972), including the continuation of dissemination of false safety and efficiency information condoning VIOXX® to the public;

(3) an award of civil penalties against Defendant, pursuant to Miss. Code Ann. § 75-24-19(1972);

(4) an award pursuant to Miss. Code Ann. § 43-13-223, *et seq.*, (1972), of an amount equal to the full amount Defendant received as a result of payments made by the Mississippi Department of Medicaid for VIOXX®, plus an additional civil penalty equal to triple the full amount received by Defendant on account of these payments;

(5) an award of compensatory damages to Plaintiff in such amount as is proved at trial;

(6) an award of punitive damages;

(7) an award of attorney's fees and prejudgment interest at the legal rate of interest, and such other equitable, declaratory and further relief as the Court may deem appropriate.

JIM HOOD, ATTORNEY GENERAL, ex rel., STATE OF MISSISSIPPI

BY: _____

Rickey T. Moore (M.S.B. #3457)
Geoffrey C. Morgan (M.S.B. #3474)
Office of the Attorney General
Post Office Box 220
Jackson, MS 39205
Telephone: (601) 359-3821

OF COUNSEL:

Sheila M. Bossier (M.S.B. #10618)
John T. Kitchens (M.S.B. #4188)
BOSSIER & KITCHENS, PLLC
1520 N. State Street
P. O. Box 55567
Jackson, MS 39296
Telephone: (601) 352-5450
Facsimile: (601) 352-5452

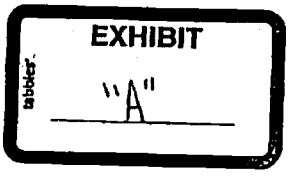
Exhibit C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

In Re: VIOXX Products Liability Litigation This Document Relates to: STATE OF LOUISIANA, ex rel. CHARLES C. FOTI, JR., ATTORNEY GENERAL Representative Plaintiff versus MERCK & CO., INC., Defendant Case No. 05-3700	MDL NO. 1657 SECTION: L HON. ELDON E. FALLON MAG. JUDGE KNOWLES

FIRST SUPPLEMENTAL AND AMENDING COMPLAINT FOR INJUNCTIVE RELIEF AND DAMAGES

NOW COME PETITIONERS, CHARLES C. FOTI, JR., a person of the full age of majority, and who currently holds the position of Attorney General for the State of Louisiana, as *parens patriae* on behalf of the State of Louisiana and its citizens, THE STATE OF LOUISIANA (the "State"), and the LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS ("DHH") (hereinafter sometimes referred to collectively as "Petitioners"), and bring this action for injunctive relief, restitution and other damages under the laws of the State of



Louisiana against the above-named defendant. This case involves the non-steroidal anti-inflammatory drug rofecoxib designed, formulated, promoted, sold and distributed by the defendant in the United States as Vioxx® ("Vioxx") from May, 1999 until its withdrawal from the market on September 30, 2004. Vioxx, as compared to other drugs in its class, caused a high incidence of injury among those individuals who ingested Vioxx, including, but not limited to heart attacks, strokes, sudden cardiac death, or death. For their Petition against the Defendant, Petitioners assert the following:

1.

Made Defendant herein is the following party:

A. **MERCK & CO., INC.**, a foreign corporation licensed to do and doing business in Louisiana, is a New Jersey corporation with its principal place of business in New Jersey. At all times relevant hereto, Merck & Co., Inc. was engaged in the business of licensing, manufacturing, distributing, and/or selling, either directly or indirectly, through third-parties or related entities, the pharmaceutical prescription drug Vioxx® ("Vioxx" or the "Product"). Petitioners allege on information and belief that Merck & Co., Inc. does business in Louisiana and the Parish of Orleans and that at all times relevant hereto it developed, manufactured, and sold in interstate commerce and in Louisiana, Parish of Orleans, the aforementioned product.

3.

Petitioners bring this action pursuant to Louisiana Constitution Art. 4, §8, La. Rev. Stat. Ann. §§ 13:5036, and 51:1401, et seq., including, but not limited to §§ 51:1405, 1407, 1408, and 1409, to obtain permanent injunctive relief, restitution, other monetary damages, costs of this suit, reasonable attorney's fees, and any and all other, further, and different relief to which Petitioners may be entitled against the Defendant by reason of the Defendant's violations of law.

4.

The acts charged in this Petition as having been done by the Defendant, were authorized, ordered and/or done by its officers, agents, employees, or representatives while actively engaged in the management and conduct of the Defendant's business or affairs.

5.

This Court has personal jurisdiction over the Defendant because the Defendant is doing business or has done business in the State of Louisiana and in this judicial district to meet due process requirements as the Defendant, directly or through agents acting with actual and/or apparent authority, has:

(a) transacted business in this state;

(b) contracted to supply or obtain services or goods in this state;

(c) intentionally availed itself of the benefits of doing business in this state;

(d) produced, promoted, sold, marketed and/or distributed its products or services in this state and, thereby, has purposefully profited from its access to this state's markets;

(e) caused tortious damage by act or omission in this state;

(f) caused tortious damage in this state by act or omission committed outside this state while (i) regularly doing or soliciting business in this state and/or (ii) engaging in other persistent courses of conduct within this state and/or (iii) deriving substantial revenue from goods used or consumed or services rendered in this state; and

(g) committed acts and omissions which the Defendant knew or should have known would cause damage and, in fact, did cause damage in this state to the Petitioners while (i) regularly doing or soliciting business in this state, and/or (ii) engaging in other persistent courses of conduct within this state and/or (iii) deriving substantial revenue from goods used or consumed or services rendered in this state.

FACTUAL ALLEGATIONS

6.

This case involves a prescription drug whose chemical name is rofecoxib, that was designed to treat osteoarthritis, rheumatoid arthritis, acute pain, and migraines. Rofecoxib was designed, formulated, patented, marketed, sold, and ultimately distributed by the Defendant under the brand name "Vioxx".

7.

Osteoarthritis, or degenerative joint disease, is characterized by the breakdown of the joint's cartilage (which cushions the ends of bones). Cartilage breakdown causes bones to rub against each other, leading to pain and loss of movement. Rheumatoid arthritis is a chronic syndrome characterized by inflammation in the lining of the joints, causing pain, stiffness, warmth, redness and swelling, leading to pain and loss of movement.

8.

Vioxx is in a class of drugs called non-steroidal anti-inflammatory drugs ("NSAIDs"). Vioxx reduces substances that cause inflammation, pain and fever. Prostaglandins are chemicals that are important in promoting inflammation and its symptoms (pain, fever, swelling and tenderness). Vioxx blocks an enzyme named COX-2 that makes prostaglandins thereby reducing the amounts of prostaglandins, and reducing inflammation and its symptoms.

9.

The United States Food and Drug Administration ("FDA") first approved Vioxx in May, 1999 for the reduction of pain and inflammation caused by osteoarthritis, acute pain and menstrual pain. Vioxx was subsequently approved to treat rheumatoid arthritis in adults and children.

10.

In June 2000, Merck submitted a safety study to the FDA entitled "Vioxx Gastrointestinal Outcomes Research" or "VIGOR" that found an increased risk of serious cardiovascular events, including heart attacks and strokes in patients taking Vioxx.

11.

In February, 2001, the FDA consulted its Arthritis Advisory Committee regarding the clinical interpretation of this new safety information.

12.

In April, 2001, the FDA implemented labeling changes which included information about the increase in risk of cardiovascular events, including heart attacks and strokes.

13.

Other studies recently suggested an increased risk of cardiovascular events, and the FDA was in the process of reviewing these studies to determine if further labeling changes were needed.

14.

On September 30, 2004, Merck voluntarily withdrew Vioxx from the market after the data safety monitoring board overseeing a long-term study of the drug recommended that the study be halted because of an increased risk of serious cardiac events, including heart attack and strokes. The risk was approximately twice that of individuals taking a placebo.

15.

Annual sales of Vioxx total approximately $2.5 billion.

16.

The Defendant aggressively marketed and sold Vioxx by misleading potential users about the product and by failing to adequately warn users of serious dangers which the Defendant knew or should have known resulted from the use of Vioxx. The Defendant widely and successfully marketed Vioxx in Louisiana and throughout the United States in order to induce widespread use. This marketing campaign resulted in numerous individuals taking Vioxx, including many Louisiana residents, and suffering serious injuries as a result, all at a time when other safer, less expensive, efficacious drugs were available. Furthermore, on information and belief, by requesting that Vioxx be placed on Louisiana's Medicaid formulary, the Defendant directly or implicitly represented to Petitioners that Vioxx was safe.

17.

On information and belief, from the time that the Defendant started developing Vioxx through the date on which the Defendant withdrew Vioxx from the market, the Defendant engaged in knowing misrepresentations with respect to the safety of Vioxx. These misrepresentations include, but are not limited to, Defendant's advertising and promotional campaigns touting Vioxx's safety; the Defendant's suppression of evidence, including its own medical/clinical research, showing that Vioxx was unsafe and posed a significant increased risk of heart attack, stroke, and other cardiovascular and/or cererbrovascular problems; and Defendant's practice of threatening and/or intimidating those physicians and scientists who attempted to protect the public by exposing Vioxx's serious, and sometimes deadly, side effects, complications, and consequences.

18.

Had the Defendant disclosed the risks and dangers associated with Vioxx, Louisiana citizens would not have taken Vioxx or been subject to its catastrophic side effects. Moreover, Petitioners would not have paid substantial sums for Louisiana Medicaid recipients' Vioxx prescriptions or still more substantial sums for the medical expenses incurred due to Louisiana Medicaid recipients' Vioxx-related injuries.

19.

On information and belief, as a result of the manufacturing, marketing, selling and distributing of Vioxx, the Defendant has reaped billions of dollars in profits at the expense of the health of individuals, including the citizens of Louisiana.

PETITIONERS WERE DAMAGED BY THE DEFENDANT'S WRONGFUL CONDUCT

20.

The Defendant falsely and deceptively misrepresented or omitted a number of material facts concerning Vioxx, including, but not limited to, adverse health effects caused by Vioxx including the frequency, severity and rapid development of these adverse events.

21.

Furthermore, through, among other things, its advertising campaigns, misleading communications with and concealment of information from the FDA, the medical community and the public, and despite its knowledge that Vioxx was dangerous, the Defendant continued to vigorously promote and advertise Vioxx.

22.

While Vioxx was on the U.S. Market, Petitioners paid a substantial amount of money for the cost of filling Vioxx prescriptions for citizens of Louisiana.

23.

The Defendant knew or should have known that Vioxx created significant risks of serious injuries, including damage to the heart, cardiovascular system, and other organs. The Defendant failed to make proper, reasonable, timely or adequate warnings about the risks associated with the use of Vioxx.

24.

By way of its wrongful misconduct, the Defendant intended to supply and did supply Vioxx to Louisiana consumers, including Louisiana Medicaid recipients, that was unreasonably dangerous and in certain instances, deadly.

25.

As a result of the Defendant's fraudulent concealment, the applicable statutes of limitations have been tolled as to all of the claims of Petitioners.

26.

Petitioners state, and intend to state, causes of action solely under the laws of the State of Louisiana and specifically are not attempting to state a cause of action under the laws of the United States of America.

27.

As a result of the manufacture, distribution, delivery and sale of the Defendant's products to purchasers within the State of Louisiana, directly or through its subsidiaries, affiliates or agents, the Defendant obtained the benefits of the laws of the State of Louisiana for its products.

FIRST CAUSE OF ACTION: REDHIBITION

28.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

29.

At all times pertinent herein, the Defendant marketed, sold, and distributed Vioxx for use by consumers, including citizens of Louisiana.

30.

The Defendant is liable to Petitioners under the Louisiana law of Redhibition because, at the time it manufactured Vioxx and sold Vioxx to citizens of Louisiana, Vioxx contained

redhibitory defects, and the Defendant knew or, alternatively, should have known, of such redhibitory defects and failed to disclose and/or concealed such defects.

31.

Had the citizens of Louisiana known of such redhibitory defects, they would not have purchased Vioxx, nor would Petitioners have approved and paid for such purchases.

32.

Had the Petitioners known of such redhibitory defects, Petitioners would not have paid for Vioxx use by Louisiana citizens.

33.

Under the Louisiana laws of Redhibition, the Defendant is liable to Petitioners for a return of the purchase price, including interest, all expenses occasioned by the sale, all damages sustained by Petitioners, as well as costs, penalties, and reasonable attorneys' fees.

SECOND CAUSE OF ACTION: STRICT LIABILITY AND FAILURE TO WARN

34.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

35.

The drug Vioxx is an unreasonably dangerous product as defined by Louisiana Revised Statute 9:2800.1 *et seq.* (the Louisiana Products Liability Act) and the defendant manufacturer is liable for all injuries proximately caused thereby.

36.

The drug Vioxx was defective at the time of its manufacture, development, production,

testing, inspection, endorsement, prescription, sale and distribution, in that, and not by way of limitation, said product and its warnings, instructions and directions failed to warn of the dangerous propensities of Vioxx, which risks were known or reasonably scientifically knowable to the Defendant. The Defendant knew or should have known of the defective condition, characteristics and risks associated with Vioxx, as previously set forth herein.

37.

At all times herein mentioned, the aforementioned product was defective, and the Defendant knew that the product was to be ingested by the user without inspection for defects therein. Moreover, the Petitioners and citizens of Louisiana neither knew, nor had reason to know at the time of the use of the subject product, of the existence of the aforementioned defects.

38.

As a result of the defective condition of the aforementioned product, Petitioners are entitled to all the damages as alleged herein.

THIRD CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY

39.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

40.

The drug Vioxx is an unreasonably dangerous product as defined by Louisiana Revised Statute 9:2800.51 et seq. (the Louisiana Products Liability Act), and the defendant manufacturer is liable for all injuries proximately caused thereby.

41.

At all times herein mentioned, the Defendant expressly warranted to Petitioners and the Louisiana citizens, and their agents and physicians, by and through statements made by the Defendant or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned product was safe, effective, fit and proper for its intended use.

42.

In purchasing, paying for, and/or utilizing the aforementioned product, Petitioners, the Louisiana citizens, and their agents and physicians relied upon the skill, judgment, representations and foregoing express warranties of the Defendant. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the use for which it was intended.

43.

As a result of the foregoing breach of express warranties by the Defendant, Petitioners suffered damages as alleged herein.

FOURTH CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY

44.

Petitioners re-allege and incorporate all preceding paragraphs of this petition as if fully set forth here, and further allege as follows:

45.

The drug Vioxx is an unreasonably dangerous product as defined by Louisiana Revised Statute 9:2800.51 et seq. (the Louisiana Products Liability Act) and the defendant manufacturer

is liable for all injuries proximately caused thereby.

46.

At all times pertinent herein, the Defendant marketed, sold, and distributed Vioxx for use by consumers, such as the citizens of Louisiana, and the Defendant knew of the use for which Vioxx was intended and impliedly warranted Vioxx to be of merchantable quality and safe and fit for its intended use.

47.

Petitioners were and are unskilled in the research, design and manufacture of the aforementioned product and reasonably relied entirely on the skill, judgment and implied warranty of the Defendant in using, purchasing, and/or paying for the aforementioned product.

48.

Contrary to such implied warranty, Vioxx was not of merchantable quality or safe and fit for its intended use, because Vioxx was unreasonably dangerous and unfit for the ordinary purposes for which it was used as described herein.

49.

As the proximate result of the Defendant's breach of implied warranty, Petitioners have sustained damages as described herein.

FIFTH CAUSE OF ACTION: UNFAIR TRADE PRACTICES

50.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth herein, and further allege as follows:

51.

The acts committed by the Defendant as alleged herein violate the provisions of the Louisiana Unfair Trade Practices Act ("LUTPA"), La. Rev. Stat. Ann. § 51:1401, et seq. Each of the previously described acts by the Defendant were "unlawful" in that they were "unfair methods of competition and[/or] unfair or deceptive acts or practices in the conduct of [Defendant's] trade or commerce," as prohibited by La. Rev. Stat. Ann. § 51:1405.

52.

As set forth previously, the Defendant has used unfair methods of competition and/or unfair and deceptive acts or practices in the design, manufacturing, and/or marketing of Vioxx and in the course of its business, all of which are unlawful under LUTPA. As Merck voluntarily withdrew Vioxx from the U.S. market, Merck could at any time voluntarily return Vioxx to the U.S. market, which would lead to additional LUTPA violations and would subject the State of Louisiana and its citizens to additional financial losses and damages. Upon information and belief, Merck has already made efforts to return Vioxx to the U.S. market. Petitioner, the Louisiana Attorney General, is specifically authorized under LUTPA to seek to enjoin (temporarily and/or permanently) all such unlawful acts pursuant to La. Rev. Stat. Ann. § 51:1407.

53.

As a direct and proximate result of the Defendant's wrongful conduct in violation of LUTPA, Petitioners have sustained financial losses in amounts as will be established at the trial of this matter, which amounts Petitioners are entitled to recover from the Defendant. Pursuant to LUTPA, Petitioners are entitled to a permanent injunction against the Defendant to prevent them

from returning Vioxx to the Louisiana market (La. Rev. Stat. Ann. § 51:1407) as well as financial restitution and such other ancillary monetary damages sustained by them (La. Rev. Stat. Ann. § 51:1408), all of which will be established at the trial of this matter. Furthermore, Petitioners, the State of Louisiana and/or DHH, which, due to the Defendant's unlawful conduct in violation of LUTPA, spent millions of dollars to purchase Vioxx for persons covered under the Louisiana Medicaid program, are entitled to all remedies afforded under La. Rev. Stat. Ann. §51:1409, including actual damages, reasonable attorney's fees, and costs. Finally, Petitioners seek any and all other and further remedies to which they are entitled under LUTPA.

SIXTH CAUSE OF ACTION: OTHER STATE LAW THEORIES OF RECOVERY

54.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

55.

At all times herein mentioned, the Defendant owed a duty to Petitioners to properly manufacture, design, formulate, compound, test, produce, process, assemble, inspect, research, distribute, market, label, package, prepare for use, sell, prescribe and adequately warn of the risks and dangers of the aforementioned product.

56.

At all times herein mentioned, the Defendant negligently and carelessly manufactured, designed, formulated, compounded, produced, processed, assembled, inspected, distributed, marketed, labeled, packaged, prepared for use and sold the aforementioned product and failed to adequately test and warn of the risk and dangers of the aforementioned product.

57.

The Defendant impliedly and/or expressly represented to Petitioners that the drug Vioxx, which they manufactured, distributed and/or sold was safe for use and would not cause the adverse health effects described herein. Despite the Defendant's knowledge to the contrary, the Defendant misrepresented to Petitioners that Vioxx was safe and/or concealed its unsafe propensities from Petitioners. Petitioners relied upon these misrepresentations to their detriment in placing Vioxx on the Louisiana Medicaid formulary and/or paying for Louisiana Medicaid recipients' Vioxx prescriptions.

58.

As a result of said negligence, carelessness, and misrepresentations of the Defendant, Petitioners have suffered damages as alleged herein.

SEVENTH CAUSE OF ACTION: UNJUST ENRICHMENT

59.

Petitioners re-allege and incorporate all preceding paragraphs of this Petition as if fully set forth here, and further allege as follows:

60.

The Defendant has been enriched from the selling and manufacturing of a defective product, and Petitioners have been correspondingly impoverished by purchasing or paying for the defective product. There is no justification or cause for Defendants' enrichment or Petitioners' resulting impoverishment.

61.

Defendants' enrichment at the expense or impoverishment of Petitioners is inequitable.

Although Petitioners have alleged that they enjoy remedies at law against Defendant, to the extent that Petitioners do not enjoy a remedy at law, Defendant should be made to return all sums unjustly obtained from Petitioners.

62.

Petitioners demand that Merck & Co., Inc. return all such monies acquired from Petitioners through the selling of Vioxx.

PRAYER FOR RELIEF

WHEREFORE, Petitioners pray as follows:

1. That the unlawful conduct alleged herein be adjudged and decreed to be unlawful and unfair methods of competition and/or unfair and deceptive acts or practices committed by the Defendant as prohibited by La. Rev. Stat. Ann. §51:1405;
2. That, pursuant to LUTPA, Petitioners be granted a permanent injunction against the Defendant to prevent it from returning the drug product trade named "Vioxx" to the Louisiana market;
3. That, pursuant to LUTPA, the Defendant be found liable, in solido, to Petitioners for financial restitution and such other ancillary monetary damages sustained by Petitioners, all of which will be established at the trial of this matter;
4. That, pursuant to LUTPA, the Defendant be found liable, in solido, to Petitioners, the State of Louisiana and/or DHH, for all remedies available to the State of Louisiana and/or DHH under La. Rev. Stat. Ann. §51:1409, including actual damages, reasonable attorney's fees, and costs;
5. That, pursuant to LUTPA, the Defendant be permanently enjoined from any other

conduct complained of herein which is determined to be in violation of LUTPA and/or that the Defendant be found liable, in solido, to Petitioners for any and all other, further, and different remedies to which Petitioners are entitled under LUTPA;

6. That Petitioners be granted all damages to which they are reasonably entitled, including, but not limited to, the return of the purchase price paid by the State of Louisiana's Medicaid program for Vioxx prescriptions,, attorney's fees to the full extent recoverable, all costs, and legal interest from the date of judicial demand until paid, due to Vioxx's redhibitory defects, the Defendant's failure to warn, the Defendant's breach of express and/or implied warranties, the Defendant's deceptive and unfair trade practices, the Defendant's negligence, the Defendant's misrepresentations, and/or the Defendant's unjust enrichment.

7. Petitioners further pray for any and all such other, further and, different relief as the nature of the case may require or as may be deemed just and proper by this Court, including, but not limited to, the recovery of all costs of this suit, judicial interest, and attorney's fees to the fullest extent recoverable by law.

8. Petitioners pray that all deposition and travel expenses be taxed as costs.

Respectfully submitted, this 5th day of May, 2006,

DUGAN & BROWNE, a P.L.C.

JAMES R. DUGAN, II, T.A. (Bar No. 24785)
DAVID L. BROWNE (Bar No. 20729)
DOUGLAS R. PLYMALE (Bar No. 28409)
3500 North Hullen Street
Metairie, Louisiana 70002
Telephone: (504) 456-8220
Facsimile: (504) 456-8624

Special Assistant Attorneys General for the State of Louisiana and Counsel for Petitioners

CHARLES C. FOTI, JR.
Attorney General

TINA VICARI GRANT
Assistant Attorney General
LOUISIANA DEPARTMENT OF JUSTICE
1885 North Third Street - 6th Floor
Baton Rouge, Louisiana 70802
Telephone: (225) 326-6020
Facsimile: (225) 326-6096

LOUISIANA DEPARTMENT OF HEALTH AND HOSPITALS

FRANCISCO H. PEREZ
General Counsel
P.O. Box 3836
Baton Rouge, Louisiana 70821
Telephone: (225) 342-1188
Facsimile: (225) 342-2232

C:\Documents and Settings\David L. Browne\My Documents\DUGAN & BROWNE\Vioxx AG\pleadings\pleading 006 1stamendedcomplaint.wpd

Exhibit D

William A. Rossbach
ROSSBACH HART BECHTOLD, PC
401 North Washington Street
Missoula, MT 59802
Telephone (406) 543-5156
Fax No. (406) 728-8998

E. Craig Daue, Esq.
BUXBAUM, DAUE & FITZPATRICK, PLLC
228 West Main, Suite A
P.O. Box 8209
Missoula, MT 59807
Telephone: (406) 327-8677
Fax No.: (406) 829-9840

Attorneys for Plaintiff

MONTANA FIRST JUDICIAL DISTRICT COURT,

LEWIS & CLARK COUNTY

THE STATE OF MONTANA,
ex rel MIKE McGRATH,
Attorney General,

Plaintiff,

-vs-

MERCK & CO., INC.,

Defendant.

Cause No. ADV-2005-879

COMPLAINT

The State of Montana, by and through the Attorney General of Montana, Mike McGrath, asserts the following claims against Merck & Co., Inc. (Merck)

I. NATURE OF THE CLAIM

This is a civil action for damages and civil penalties for violations of the Montana Food Drug and Cosmetic Act, the Montana Consumer Protection Act, and the other causes of action stated herein. The action is brought by the Montana Attorney General in the exercise of his common law and statutory powers. At all times relevant, Defendant Merck knew and had reason to know that its drug, Vioxx, was not safe for its intended purpose; that

Vioxx put users at risk for cardiovascular injuries and could cause potentially fatal myocardial infarctions, both obvious and silent, as well as other adverse cardiovascular events, including ischemic strokes and death. Merck also knew that Vioxx was no more effective than other traditional, and much less expensive, non-steriodal anti-inflammatory drugs commonly available for treatment of acute and chronic pain and knew that, except in a very few patients with severe gastrointestinal problems, the use of Vioxx was neither medically nor financially justified. Despite this knowledge, Merck misrepresented the safety of Vioxx and manufactured, advertised, promoted, marketed, and sold Vioxx as a safe prescription medication when it knew that was not true. Moreover, Merck misrepresented the effectiveness of Vioxx in comparison to other non-steriodal anti-inflammatory drugs and misrepresented and over-promoted its use when it was not medically justified. As a consequence of Merck's false advertising, promotion, and marketing of Vioxx and other misrepresentations, the State of Montana and its private citizens and corporate entities were injured and damaged and caused to spend money on Vioxx that was not medically justified and that actually caused cardiovascular injuries, disability, and death.

II. DEFENDANT'S CONDUCT

1. The human body naturally produces two forms of cyclo-oxygenase enzymes (COX-1 and COX-2) that contribute to and are associated with inflammation and pain. Non-steriodal anti-inflammatory drugs (NSAIDs) have the potential to relieve pain and inflammation by inhibiting the production of these enzymes. Many NSAIDs have been developed for human use since aspirin was first formulated in 1897. Traditional NSAIDs like aspirin, ibuprofen, and naproxen reduce pain and inflammation by inhibiting production of both COX-1 and COX-2 enzymes.

2. Merck developed Vioxx during the 1990s. Vioxx is in the class of NSAIDs known as COX-2 inhibitors. COX-2 drugs inhibit the production of the COX-2, but not the COX-1 enzyme. COX-2 inhibitors tend to create less irritation to the stomach and intestines than the earlier NSAIDs that inhibit both COX-1 and COX-2. However, although they reduce gastrointestinal irritation, Vioxx and other COX-2 drugs also increase

cardiovascular risk. As shown below, Merck has known this since early in its development of Vioxx. Nevertheless, because of the competition with other companies for market share for treatment of acute and chronic pain and particularly arthritis, Merck wanted to get Vioxx onto the market as quickly as possible.

3. Dr. Alan S. Nies, a Merck scientist who led the Vioxx development program in the 1990's, developed a plan in 1996 to expedite federal approval of Vioxx because of fear that Celebrex, a competing drug by Pfizer, would get approval first. Dr. Nies' 1996 plan identified the Celebrex market goal of late 1998 and set the same goal for Vioxx. The document also noted an "accelerated and compressed" drug development strategy by beginning some clinical studies before others were finished.

Before Obtaining FDA Approval, Merck Knew That Vioxx Increased the Risk of Heart Attacks.

4. Even while it was working to expedite approval of Vioxx, Merck knew very early that Vioxx lacked the beneficial anti-platelet effects of aspirin and aspirin-like NSAIDs. At the site of an injury, blood platelets clump together to help form a clot and prevent the loss of blood. When blood clots form inside arteries supplying blood to the heart or brain, heart attacks and strokes can occur. Aspirin and certain other NSAIDs reduce platelet aggregation and the formation of clots, thereby reducing the risk of heart attack and stroke in many patients.

5. In 1996, a Merck employee discussing a proposed trial to compare Vioxx to other NSAIDs stated that if patients receiving Vioxx in the trial were not allowed to take aspirin, "there is a substantial chance that significantly higher rates" of cardiovascular problems would occur in the patients taking Vioxx.

6. Merck official, Briggs Morrison, stated in a February 25, 1997, e-mail that unless patients taking Vioxx in the trial also took aspirin, "you will get more thrombotic events and kill [the] drug."

7. In a 1997 e-mail addressing the subject of whether patients taking Vioxx in the trial should also take aspirin, Merck scientist, Alise Reicin, stated that "the possibility of

increased CV [cardiovascular] events is of great concern." Ms. Reicin suggested that patients with a high risk of cardiovascular problems be excluded from the trial so that the increased rate of cardiovascular problems in the group taking Vioxx "would not be evident."

8. By April 1998, Merck scientists had also learned that COX-2 inhibitors, such as Vioxx , reduce the production of prostacyclin, a naturally occurring compound in the body that prevents blood platelets from clumping together. Merck, therefore, knew that Vioxx not only lacks the beneficial anti-platelet effect of aspirin and certain other NSAIDs, it also disables one of the blood vessels' main defenses against the clumping of platelets.

9. In 1998, Merck sought patent protection for a way to reduce cardiovascular problems in COX-2 inhibitors such as Vioxx. Merck obtained a patent for such a drug, or combination of drugs, in September 1999 from the World Intellectual Property Organization.

10. Before Vioxx was approved for sale in the United States, Merck knew that it contributed to the aggregation of blood platelets, putting users at risk for adverse cardiovascular effects, and knew that it could cause potentially fatal myocardial infarctions, both obvious and silent, and cerebrovascular events such as ischemic strokes and death.

11. Merck received approval from the Federal Food and Drug Administration (FDA) in May 1999 to sell Vioxx in the United States for the treatment of osteoarthritis and acute pain in adults.

After Obtaining FDA Approval, Merck Knew of Additional Evidence That Vioxx Increases the Risk of Heart Attacks

12. In 1999, Merck initiated a study of Vioxx titled "Vioxx Gastrointestinal Outcomes Research," or VIGOR. In March 2000, the results of VIGOR showed that patients in the study taking Vioxx suffered heart attacks at a rate 4 times higher than patients taking the older NSAID naproxen. Later analysis of the VIGOR data revealed that the rate was actually 5 times higher.

13. On March 9, 2000, Dr. Edward Scolnick, a senior Merck research official, sent an e-mail acknowledging that cardiovascular events caused by Vioxx "are clearly there," and that the cardiovascular effect "is mechanism based as we worried it was."

14. In 2000, Merck officials issued a "Confidential Memorandum of Invention." In that document, they stated that because Vioxx might cause cardiovascular problems, Merck should consider applying for a patent on combining Vioxx with another drug that would protect against cardiovascular problems from blood clots.

15. In March 2001, Merck filed a patent application for a drug combining Vioxx with a thrombaxane synthase inhibitor to help protect against the clotting problems caused by Vioxx. The application lists Dr. Edward Scolnick as the primary inventor.

16. Although Merck sought patent protection for ways to lessen the cardiovascular risks of Vioxx, it never produced such drugs. Instead, Merck continued to manufacture and market Vioxx as a stand alone drug.

17. In June of 2000, pharmaceutical industry-sponsored studies presented at the European United League Against Rheumatism (EULAR), an organization in which Merck was a member and a corporate sponsor, showed that Vioxx use resulted in statistically significant increases in hypertension and myocardial infarction.

18. In the journal *Pharmacy Today*, Merck publicly denied the validity of the results of the studies presented at the June 2000 EULAR study, especially with respect to the hypertension problems identified in that study.

Merck Publicly, and By Direct Communication to Prescribing Doctors, Made False and Misleading Statements about the Safety and Efficacy of Vioxx

19. The results of the VIGOR trial were announced to the public on March 27, 2000, and were published in the *New England Journal of Medicine* on November 23, 2000. The VIGOR trial showed that patients receiving Vioxx were 5 times more likely to suffer a heart attack than those who received the older NSAID naproxen.

20. To counteract this adverse information, Merck improperly pooled internal unpublished data to produce a misleading promotional device, titled the "Cardiovascular Card," which misrepresented the true risk of adverse cardiovascular events of Vioxx compared to traditional NSAIDs. On April 28, 2000, Merck issued a bulletin instructing its salespeople to use this Cardiovascular Card (CV Card) if doctors asked them about

cardiovascular risks of Vioxx. Instead of telling doctors the truth Merck knew about the cardiovascular risk shown in the VIGOR study, the bulletin required salespeople to point doctors to charts which listed "Overall Mortality Rates" purporting to show that patients on Vioxx were 11 times less likely to die than patients on other NSAIDs and were 8 times less likely to die of heart attacks and strokes. Merck told its salespeople to use the CV Card to "[e]nsure that the physician agrees that the cardiovascular events seen with Vioxx in OA clinical trials were low and similar to [other NSAIDs]."

21. The April sales bulletin instructed salespeople never to raise the subject of cardiovascular risks of Vioxx when talking to doctors. Merck treated questions by doctors about the cardiovascular risks of Vioxx as "obstacles." The April 28, 2000, Merck bulletin states: "The Cardiovascular Card is an obstacle handling piece and should only be used with physicians in response to their questions regarding the cardiovascular effects of Vioxx." Merck told its salespeople never to leave a CV Card with a doctor or allow a doctor to make a copy of the card.

22. On February 8, 2001, the FDA conducted an Arthritis Advisory Committee meeting at which questions about the safety of Vioxx were extensively reviewed. At the meeting, Merck presented a large, pooled analysis of all Vioxx trials. In response, FDA officials told the advisory committee that pooling data from different studies to assess safety, as Merck was doing, was fundamentally flawed.

23. The FDA Arthritis Advisory Committee concluded that doctors should be told that the VIGOR study showed "an excess of cardiovascular events in comparison to naproxen."

24. The next day, contrary to the FDA Arthritis Advisory Committee recommendation, Merck sent another emergency bulletin to its salespeople stating: "DO NOT INITIATE DISCUSSIONS ON THE FDA ARTHRITIS ADVISORY COMMITTEE . . .OR THE RESULTS OF THE . . . VIGOR STUDY." The bulletin further ordered salespeople to "[s]tay focused on the EFFICACY message for Vioxx."

25. The bulletin referred to its contents as "Updated Obstacle Responses," and closed by reminding salespeople: "Do not proactively discuss the Advisory Committee Meeting or VIGOR."

26. On May 22, 2001, the *New York Times* published an article raising questions about VIGOR and the cardiovascular safety of Vioxx. The very same day, Merck issued a press release responding to the *New York Times* article. The press release stated: "Merck Confirms Favorable Cardiovascular Safety Profile of Vioxx." The press release referred to the pooled data from pre-approval studies and claimed that: "there was no difference in the incidence of cardiovascular events, such as heart attacks, among patients taking Vioxx, other NSAIDs and placebo."

27. A day later, in response to the unfavorable press, Merck sent another emergency bulletin to its field sales staff, once again instructing them to counter the *Times* article by displaying the CV Card and highlighting data on the card suggesting that Vioxx was safer than other NSAIDs. It advised its sales representatives to tell doctors that Merck's data showed that cardiovascular mortality was actually 8 times less than other NSAIDs.

28. In July 2001, an article in *WEB MD* quoted an FDA Study stating: "[T]he study found that Vioxx cut the occurrence of ulcers and other gastrointestinal problems by half compared with the over-the-counter NSAID Aleve. But the study showed that people taking Vioxx had four times the risk of a heart attack."

29. In response, Merck's spokeswoman, Christine Fanelle, replied that the "risk was negligible," and that "it appeared to increase the risk of a heart attack because Aleve, like aspirin, actually reduces heart attack risks."

30. On August 22, 2001, the *Journal of the American Medical Association* (JAMA) published an article authored by cardiologists Eric J. Topol, M.D., Debarata Mukherjee, M.D., and Steven E. Nessen, M.D. of the Cleveland Clinic Foundation entitled, "Risk of Cardiovascular Events Associated with Selective Cox-2 Inhibitors." The JAMA article reported the Cleveland Clinic's evaluation of two randomized trials of more than 15,000 patients, comparing Pfizer's Celebrex in a study called CLASS and Merck's VIGOR Study

involving Vioxx. The Cleveland Clinic reported that: "[T]he annualized myocardial infarction rates for COX-2 inhibitors in both VIGOR and CLASS were significantly higher than that in the placebo group . . . ."

31. The day before the JAMA article was published, Merck issued a statement claiming: "We have additional data beyond what they cite, and the findings are very, very reassuring. Vioxx does not result in any increase in cardiovascular events compared to placebo."

32. On that same day, Merck executive, Jo Jerman, also delivered a voice mail to company field representatives reassuring them and instructing them again to use the CV Card if asked about cardiovascular effects, reminding them that the card showed that cardiovascular mortality rates were similar for Vioxx and other NSAIDs.

33. On August 23, 2001, the day after the JAMA article was published, Merck stated in another press release: "The Company stands behind the overall and cardiovascular safety profile . . . of Vioxx."

34. Each time there was any public concern raised about the safety of Vioxx, Merck responded by instructing its field staff to focus on using the misleading CV Card to overcome any hesitation or concerns by the prescribing doctors.

35. In a 2001 direct letter to doctors, Merck seriously understated the heart risks faced by patients taking Vioxx. Merck reported that, in patients taking Vioxx in the largest clinical trial of the drug ever, only 0.5 percent had incurred "cardiovascular events," or heart and circulation problems. In fact, 14.6 percent of the Vioxx patients had cardiovascular problems while taking the drug, according to Merck's own report on the study to federal regulators. In addition, 2.5 percent had serious problems, like heart attacks.

36. On September 17, 2001, the FDA issued a WARNING LETTER to Merck stating that: "[Y]our claim in the press release that Vioxx has a 'favorable cardiovascular safety profile,' is simply incomprehensible, given the rate of MI and serious cardiovascular events compared to naproxen. The implication that Vioxx's cardiovascular profile is superior to other NSAIDS is misleading . . . ." The WARNING LETTER also makes the following